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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,006	02/04/2000	Dr. Paddy Jim Baggot	249/127	9604

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	16

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/499,006	Applicant(s) BAGGOT, DR. PADDY JIM	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-24* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-16, 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to paper no. 13, filed March 25, 2002, and paper no. 15, filed July 1, 2002. Claim 24 has been added, and claims 15-24 are now pending.

Election/Restriction

2. Applicant's election without traverse of Group II in Paper No. 13 is acknowledged.

3. Claim 17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15-16 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of "identifying a presence of Down Syndrome in a fetus" comprising obtaining an amniotic fluid specimen, identifying "a quantity for each metabolite that is present in the amniotic fluid specimen," comparing a profile of metabolites in the specimen with a control profile, wherein Down Syndrome is identified when quantities of a subset or plurality of metabolites are found to differ in the patient

profile as compared to the control profile. It is unpredictable as to whether one of skill in the art could use the claimed invention. The specification discloses that the mean and median levels of several metabolites in a population of "Down Syndrome patients" differ from the mean and median levels found in a population of "normal patients" (see data presented at pp. 7-16). However, the specification does not disclose the identity of the body fluid employed to produce the data provided in the specification. For example, it is unknown based on the guidance provided in the specification as to whether the levels disclosed in the specification were detected in, e.g., the blood of patients suffering from Down Syndrome or in amniotic fluid obtained from mothers carrying fetuses with Down Syndrome (as recited in the instant claims). Thus, the specification does not provide evidence that one may diagnose or identify Down Syndrome in a fetus by comparing levels of metabolites in amniotic fluid. Further, it is unpredictable as to how the relative levels of metabolites detected in, e.g., the blood of a patient suffering from Down Syndrome would relate to the relative levels of metabolites found in the amniotic fluid of a mother carrying a child with Down Syndrome. Absent guidance from the specification, one of skill in the art may rely on the teachings of the prior art for enablement of a claimed invention. However, in the instant case, the prior art is silent with respect to methods in which differences in the quantities of a plurality of metabolites in amniotic fluid are employed in the diagnosis of Down Syndrome. Thus, neither the specification nor the art provide evidence that one may diagnose Down Syndrome in a fetus by comparing levels of a group of amniotic fluid metabolites with levels from a normal control population. Further, neither the specification nor the art establish a correlation

between levels of metabolites in amniotic fluid surrounding a fetus with Down Syndrome and, e.g., levels in blood of an adult Down Syndrome patient. As it is unknown as to whether differences in amniotic fluid metabolite levels actually exist in Down Syndrome patients as compared to normal patients, it is further unpredictable as to whether any quantity of experimentation would be sufficient to allow one of skill in the art to practice the invention as claimed, and the level of experimentation required to use the claimed invention is therefore undue. Further, it is noted that the teachings of the specification indicate that only particular metabolites exhibit significant differences in Down Syndrome patients as compared to normal patients. Were the specification to have identified the body fluid employed in obtaining the data at pages 7-16, the teachings of the specification would enable one of skill in the art to identify Down Syndrome by detecting differences in a levels of a subset/plurality of metabolites that were shown by Applicant to exhibit significant differences in a Down Syndrome population as compared to a normal population. However, as it is unpredictable as to whether any other metabolites exhibit such significant differences in levels, it would require undue experimentation to practice the invention as it is broadly claimed in claims 15 and 18-21.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15-16 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-16, 18-20, and 24 are indefinite over the recitation of the phrase "wherein the control profile lists the quantity for each respective metabolite of the control profile that is present in persons without Down Syndrome" in claim 15. First, there is insufficient antecedent basis for the limitation "the quantity for each respective metabolite of the control profile that is present in persons without Down Syndrome." Second, this language does not make clear whether "the quantity....that is present in persons without Down Syndrome" refers to, e.g., the mean/median quantity present in amniotic fluid of healthy fetal patients, or whether the claims would encompass comparisons with any type of "control profile," e.g., levels obtained from the blood of healthy adults, etc. Clarification is required.

Claims 15-16, 18-20, and 24 are indefinite over the recitation of the phrase "a subset of metabolites of the patient profile has a different quantity than each respective metabolite of the control profile" in claim 15. It is unclear as to whether this language is intended to require the comparison of a single "quantity" of a "subset of metabolites" with "each respective metabolite of the control profile" (as the claim language suggests), or whether applicant's intent is to require comparison of the quantity of each metabolite in the subset with the quantity of that metabolite in the control profile. Clarification is required.

Claims 21-23 are indefinite over the recitation of the language "wherein the control profile lists a quantity for each metabolite present in the amniotic fluid specimen for a population of patients without Down Syndrome" and "abnormal quantities of those metabolites in a patient known to have Down Syndrome" in claim 21. It is unclear as to

whether these recitation are intended to refer to quantities present in amniotic fluid surrounding a fetus with Down Syndrome, or whether the claims are intended to encompass comparisons with, e.g., quantities present in other types of body fluids from, e.g., adult patients. Clarification is required.

Conclusion

8. It is noted that the prior art does not teach or suggest methods of identifying the presence of Down Syndrome in a fetus in which an amniotic fluid sample is obtained and in which the levels of any of the combinations of metabolites recited in present claims 16 and 22-24 are detected to achieve detection of Down Syndrome.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
October 17, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600